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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/624,911 | 07/21/2003 | Miljenko Dunic | 03818/000M728-US0 | 7098 |

7590 10/22/2004

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| EXAMINER |
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PESELEV, ELLI

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| ART UNIT | PAPER NUMBER |
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1623

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,911

Applicant(s)

DUMIC ET AL.

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-31, 39 and 40 is/are allowed.
- 6) ☒ Claim(s) 32-38 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claims 37 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the reasons set forth in the Office Action of May 14, 2004.

Applicant's arguments filed September 14, 2004 have been considered but have not been found persuasive.

Applicant contends that the Culic et al articles and the International Publication NO. WO 02/087596 disclose that macrolides modulate inflammatory responses and that zithromycin can be used for the therapy of neutrophil-dominated non-infective inflammatory diseases. This argument has not been found persuasive since the instant claims have not been limited to the therapy of neutrophil-dominated non-infective inflammatory diseases. Further, the articles by Culic et al do not show the use of azithromycin for the treatment of any anti-inflammation-related diseases but merely indicate the potential for such treatment. The articles suggest that further experimentation is needed to determine whether azithromycin is useful for the treatment of inflammation related diseases.

Claims 32-38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Karimian et al (U.S. Patent No. 6,245,903).

Applicant's arguments filed September 14, 2004 have been considered but have not been found persuasive.

Applicant contends that pure amorphous azithromycin of the present invention has superior and unexpected properties when compared to the amorphous azithromycin

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described by Karimian et al. This argument has not been found persuasive. Example 19 on page 35 of the specification compares the intrinsic dissolution rates for the new amorphous azithromycin prepared according to the procedure of Example 11 and azithromycin dihydrate i.e. the comparison has not been made to the amorphous azithromycin disclosed by Karimian et al. Further, the claimed amorphous azithromycin is not limited to the product prepared by Example 11. Note that Example 11 calls for orthorhombic pseudopolymorph to be dried at a temperature of 80 C, under reduced pressure of 2 kPa to constant weight. Claims 32-38 encompass amorphous azithromycin prepared by the process of claim 1. All claim1 states is that orthorhombic isostructural pseudopolymorph of azithromycin is converted to substantially pure amorphous azithromycin i.e.the steps of Example 11 are not stated in claim 1. Therefore, the claimed amorphous azithromycin is not limited to the product as prepared in accordance with Example 11 and still reads on the amorphous azithromycin disclosed by Karimian et al.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

elli peselev
ELLI PESELEV
PRIMARY EXAMINER
GROUP 1500